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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO.       |
|---|-------------|----------------------|-------------------------|------------------------|
| 10/555,586  | 11/04/2005  | Li-ming Gan          | 100916-1P US            | 4411                   |
| 44992 7590 08/28/2007<br>ASTRAZENECA R&D BOSTON<br>35 GATEHOUSE DRIVE<br>WALTHAM, MA 02451-1215 |             |                      | EXAMINER<br>SHEN, BIN   |                        |
|   |             |                      | ART UNIT<br>1657        | PAPER NUMBER           |
|   |             |                      | MAIL DATE<br>08/28/2007 | DELIVERY MODE<br>PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/555,586             | GAN ET AL.          |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Bin Shen               | 1657                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,3-8,13-16,23 and 25-29 is/are pending in the application.
- 4a) Of the above claim(s) 1, 25-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3-8,13-16 and 23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>          </u>  | 6) <input type="checkbox"/> Other: _____                          |

#### **DETAILED ACTION**

The IDS received 11/4/2005, the preliminary amendment received 11/4/2005 have been entered.

#### ***Election***

Applicant's election with traverse of Group II, in the reply filed on 6/26/2007 is acknowledged. The traversal is on the ground(s) that the Groups that the special technical feature was not shown by the cited prior art (Lendon et al.). However, the special technical feature was shown in Rekhter et al. (Circ Res. 1998 83:705-713). Applicant's request of rejoining of Group II and III is considered reasonable, thus Groups II and III are rejoined.

The requirement for restriction between all other groups (except group II and III) is still deemed proper and is therefore made FINAL.

Claims 1, 25-29 are nonelected and thus are withdrawn from further consideration.

Only claims 3, 4-8, 13-16, 23 are presented for examination on the merits.

#### ***Specification***

1. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1657

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 3, 16, 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Rekhter et al. (Circ Res. 1998 83:705-713).

Rekhter et al. teach a method for determining the ability of a test compound to enhance plaque stability comprising: administering a test compound to an animal (page 706, left column, lines 2-5), excising the plaque (page 706, left column, 2<sup>nd</sup> full paragraph), subjecting the plaque to pressure, measuring the amount of pressure required to rupture the plaque and comparing with control to assess whether or not the compound enhance plaque stability (page 707, left column, 2<sup>nd</sup> full paragraph); wherein the amount of pressure is measured using a force transducer (page 707, left column, 2<sup>nd</sup> full paragraph, line 15); wherein the plaque is an aortic plaque (page 711, left column, 1<sup>st</sup> full paragraph, line 7)..

Therefore, the cited reference is deemed to anticipate the instant claims above.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Art Unit: 1657

3. Claims 3, 4-8, 13-16, 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Rekhter et al. in view of Lemaitre et al. (J of Clinical Investigation 2001 107(10):1227-1234).

Rekhter teaches what is above.

Rekhter does not teach a control animal that has not been treated with the test compound, the test animal is a transgenic or knock-out animal, the animal is a mouse.

However, Rekhter suggest that their animal model can be used to determine if a drug treatment influence plaque stability (page 710, left column, 4<sup>th</sup> full paragraph), developing of alternative plaque-rupture models (page 712, right column, lines 1-2).

Lemaitre teaches a transgenic mouse model (Apo E knockout mice-see title) for study of atherosclerotic plaque rupture (abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the transgenic mouse model of Lemaitre's to test compound that enhance plaque stability because Rekhter teach that animal models are essential for development of diagnostic imaging technique (page 712, left column, 3<sup>rd</sup> full paragraph). One would have been motivated to make the modification because Lemaitre teaches that apoE knockout mice rapidly develop complex atherosclerotic lesions that are very similar to those of humans (page 1227, right column, 1<sup>st</sup> full paragraph), and would reasonably have expected success in view of both Rekhter and Lemaitre's teachings. The adjustment of particular conventional working conditions (e.g., tensile force) is deemed merely a matter of judicious selection

Art Unit: 1657

and routine optimization which is well within the purview of the skilled artisan having the cited reference before him/her.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

#### **Conclusion**

4. No claim is allowed.

Certain papers related to this application may be submitted to Art Unit 1657 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily

Art Unit: 1657

from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.


For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Bin Shen, Ph.D., whose telephone number is (571) 272-9040. The examiner can normally be reached on Monday through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to her office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571) 272-0925.

*B Shen*

Art Unit 1657

  
RALPH GITOMER  
PRIMARY EXAMINER  
GROUP 1200